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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,005	08/07/2007	**Roger Graham Hall**	70360	4633

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EXAMINER	
JAISLE, CECILIA M	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
04/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

department-gso.patent@syngenta.com

Office Action Summary	Application No.	Applicant(s)	
	10/597,005	HALL ET AL.	
	Examiner	Art Unit	
	Cecilia M. Jaisle	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07-06-2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Lack of Unity

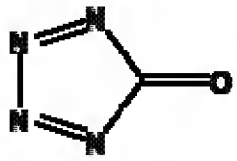
Applicants' election of Group IV, claims 1-16, with traverse in the May 15, 2008 Response is acknowledged. Claims 1-16 are under examination.

Rejections Under 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because, while the specification enables a method of making the compounds of Examples 1.11-1.13, 1.27-1.29, 1.43-1.45 and 1.58, the specification does not enable a method of making the claimed compounds where HET is 1,2,3,4-tetrazol-5-one. The compound



1,2,3,4-tetrazol-5-one has no available H. Thus, it cannot be attached to the rest of the molecule, let alone have a substituent Riii. The compounds of claims 1-16, as defined, are structurally impossible and the present specification does not show how to make or how to use these compounds. Although the examiner recognizes that she was the one to introduce this misnomer (Lack of Unity requirement, Apr. 15, 2008), that does not change the facts. **It is suggested that the intended HET ring be illustrated**

structurally, rather than by a name, to avoid possible misinterpretation. It is further noted that this specification is seen to enable only the R2 ring-isomer of Examples 1.11-1.13, 1.27-1.29, 1.43-1.45 and 1.58.

The process (pages 6-9, *inter alia*) fails to teach commercial availability of or how to make all starting materials and intermediates required to prepare the compounds encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make, and thus to use, the invention commensurate in scope with these claims.

Because neither the prior art, nor the present specification nor both of them together teach how to prepare compounds encompassed by the claims, it follows as a necessary corollary that the method of using these compounds is not enabled.

Applicants' attention is drawn to the Revised Interim Utility and Written Description Guidelines, 66 FR 1092-1099 (2001), emphasizing that "a claimed invention must have a specific and substantial utility." MPEP 2163, *et. seq*. This application's disclosure is insufficient to enable making the claimed compounds, absent disclosure of a valid method of preparing the claimed compounds as noted in the paragraph above. The state of the art indicates the requirement for undue experimentation.

Many factors require consideration when determining whether sufficient evidence supports a conclusion that a disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue." MPEP 2164.01(a). These factors include: (1) the claim breadth; (2) the nature of the invention; (3) the state of the prior art; (4) the level of predictability in the art; (5) the amount of direction provided by the

inventor; (6) the presence of working examples; and (7) the quantity of experimentation needed to make the invention based on the content of the disclosure. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)(reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). See also *In re Goodman* 29 USPQ2d 2010, 2013 (Fed. Cir. 1993). Application of these factors to the present application supports the determination that the present disclosure fails to satisfy the enablement requirement:

(1) Breadth of claims.

(a) Scope of the compounds. The claims cover substituted 1,2,3,4-tetrazol-5-one compounds.

(b) Scope of the methods of preparing the compounds. The scope of the methods is stated above and below in Point (3) Direction or Guidance. The specification contains insufficient disclosure of the preparation of the claimed compounds. The method scope is discussed above, and the specification does not disclose preparation of the claimed compounds, particularly failing to show the source of the necessary starting materials and intermediates or the methods of preparation of the required starting materials and intermediates.

In *In re Albrecht, et al.,* 185 USPQ 590, 594 (CCPA 1975), the claimed compounds were rejected for lack of enablement, because the specification failed to show all necessary starting materials required to prepare all claimed compounds. Appellant attempted to rely on a US patent (Anderson) to show such starting materials. J. Baldwin confirmed that, when appellant's claims are rejected as non-

enabling for failure to show all starting materials needed to prepare their claimed compounds, appellant must show specifically all such starting materials:

> However, we fail to find all of the missing [starting materials] ... necessary to prepare appellants' claimed compounds. ... It is incumbent upon appellants to show where in the Anderson *disclosure* one of ordinary skill in the art would glean the necessary information required to satisfy the enablement requirement of the first paragraph of 35 USC 112. The Anderson patent specification contains thirty examples and nine columns of text. Appellants have not pointed out precisely where enablement lies in that disclosure. It is incumbent upon appellants to rebut the assertion that their specification is not enabling.

In re Wands, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988) similarly noted the requirement of the availability of biological organisms when they were necessary starting materials to support enablement of the claims:

> A deposit has been held necessary for enablement where the starting materials ... are not readily available to the public. Even when starting materials are available, a deposit has been necessary where it would require undue experimentation to make the ... invention from the starting materials. ... No deposit is necessary if the biological organisms can be obtained from readily available sources or derived from readily available starting materials through routine screening that does not require undue experimentation.

(2) The nature of the invention and predictability in the art: "[T]he scope of enablement varies inversely with the degree of unpredictability of the factors involved" and the ability to make all claimed compounds is considered to be unpredictable because all necessary starting materials and intermediates have not been shown to be available. *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970). In the instant case, the disclosure does not sufficiently address preparation of all claimed compounds.

(3) Direction or Guidance: The specification teaches methods to make certain compounds, but does not teach methods and required starting materials and

intermediates necessary to prepare the compounds of claims 1-16. Neither the prior art, nor the present specification nor both of them together teach how to prepare all claimed compounds, especially considering the number of position isomers and further substituents encompassed thereby.

(4) State of the Prior Art: Formation of compounds is highly species-specific in organic chemistry. *Albrecht* and *Wands*, discussed above, stand as evidence of the prior art acknowledgement that unless starting materials to prepare all compounds within the scope of the claims are available, the claims are not enabled. Applicants must show all necessary starting materials or limit the claims accordingly.

(5) Working Examples: The specification has been discussed in Point 3) Direction or Guidance, above. Pharmacological and chemical activities in general are unpredictable. In applications involving physiological and chemical activity, as the present,

> The first paragraph of 35 U.S.C. 112 effectively requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.
>
> *Plant Genetic Syst. v. DeKalb Genet.*, 65 USPQ2d 1452, 1456 (Fed. Cir. 2003).

"[T]he scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970).

(6) Skill of those in the art: The state of the art supports that to successfully prepare all compounds within the scope of the claims requires specific individualized disclosure.

(7) The quantity of experimentation needed: Based on the disclosure content, one skilled in the pharmaceutical arts would have an undue burden to make and use the

invention, since the disclosure gives the skilled artisan inadequate guidance regarding making all claimed compounds, as stated above.

Discussion of the above factors demonstrates that the present application sufficiently lacks enablement of the present claims. In view of the claim breath, the unpredictability of methods of making the claimed compounds, one of ordinary skill in this art would undergo an undue amount of experimentation to make the instantly claimed invention commensurate in scope with the claims.

MPEP 2164.01(a) states,

> A conclusion of lack of enablement means that, based on the evidence regarding each of the above [Wand] factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

This is a circumstance where the "specification is evidence of its own inadequacy." *In re Rainer*, 153 USPQ 802, 807. The claimed compounds cannot be simply willed into existence. *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 states:

> The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist ... the examples of the '881 patent do not produce the postulated compounds ... [T]here is ... no evidence that such compounds even exist.

The same circumstance appears true here. Applicants must show making all claimed compounds or limit the claims accordingly.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J.D. whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cecilia M. Jaisle

/James O. Wilson/
Supervisory Patent Examiner, AU 1624